

Figure 2

350

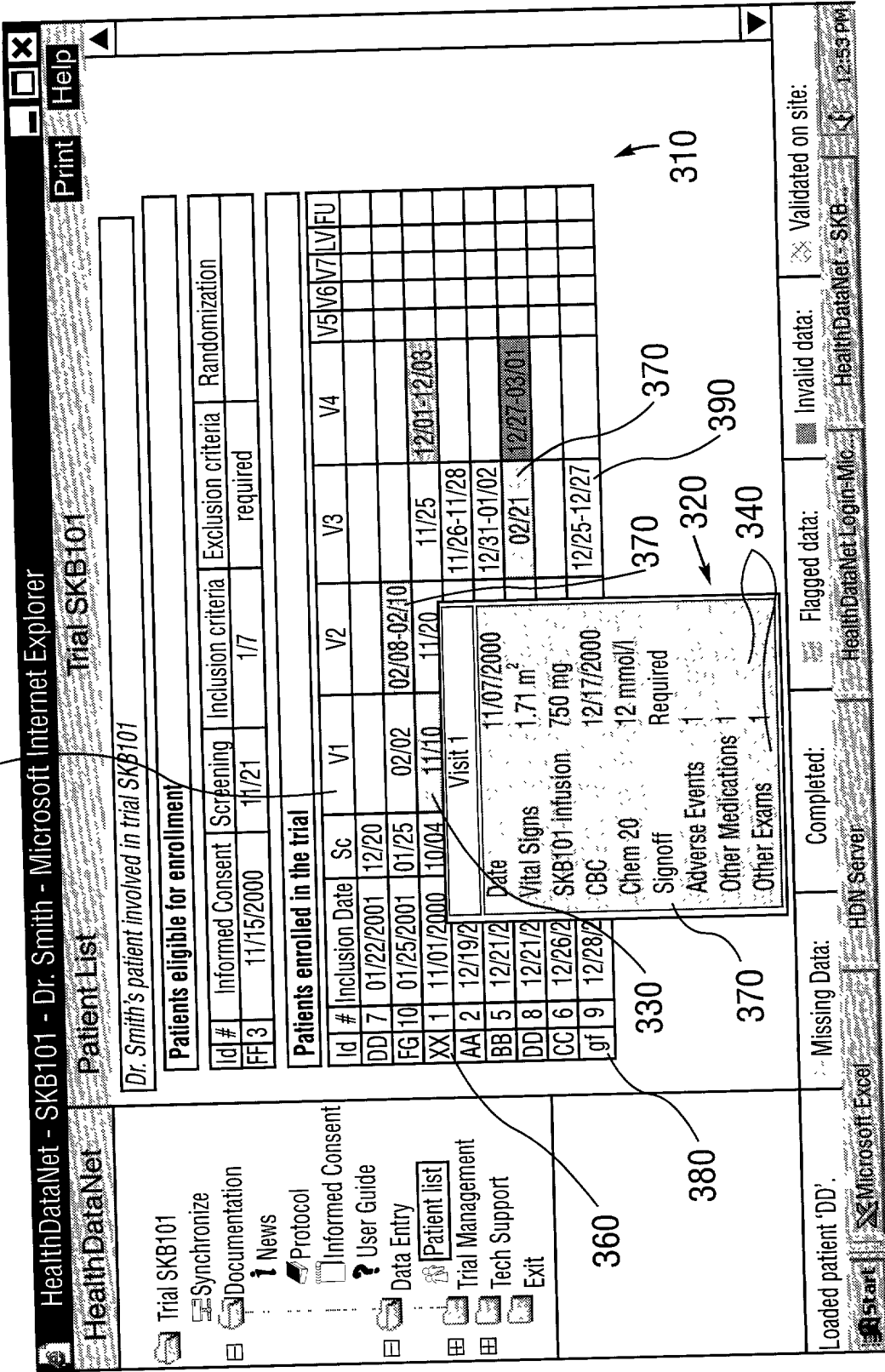


Figure 3

200

420

Patient gf (# 9) Trial SKB101

Initials: gf Number: 9

Random #: 556363 Unit #: 122

Status: Included

Consent: 12/06/2000

Sex: Female

Inclusion: 12/28/2000

Age: 45

End:

430

410

440

450

	Screening	Visit1	Visit2	Visit3	Visit4	Visit5	Visit6	Visit7	Last Visit
Date	12/05/2000	12/12/2000	12/19/2000	12/25-12/27	+ [6-8]	+ [6-8]	+ [6-8]	+ [6-8]	+ [6-8]
Inclusion criteria	OK								
Exclusion criteria	OK								
Randomization	#556363								
Medical History	12/28/2000								
Tumor Assessment	4 cm								
Pregnancy test	Negative								
GOG	1								
Physical Exam	12/28/2000		01/24/2001	Brief	Brief	Brief	Brief	Brief	Brief
Vital Signs / BSA	1.74 m <sup>2</sup>	1.66 m <sup>2</sup>	before	before	before	before	before	before	before
CA-125	65 U/ml								
SKB101 infusion	700 mg	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>
CBC	01/25/2001	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion
Chem 20	140 mmol/l	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion
Toxicity Assessment									
Signoff	required	required	required	required	required	required	required	required	required
Adverse events		to check	to check	to check	to check	to check	to check	to check	to check
Other Medications	1	1	1	1	1	1	1	1	1
Other Exams	to check	to check	to check	to check	to check	to check	to check	to check	to check

Figure 4



Data validation

Trial SKB101

Print

Help

Add Patient

## Validation status of collected forms

Not/ Available Data

620

Confirmed Data

Initials	Patient	Form	Visit
XX	1	Date: 10/04/2000	Screening
AA	2	Date: 11/15/2000	Visit 1
gf	9	SKB101 infusion: 700 mg	Visit 1
DD	8	SKB101 infusion: 800 mg	Visit 1
XX	1	Signoff: 11/09/2000	Screening

Flagged Data

630B

630A

Initials	Patient	Form	Visit
FF	3	CA-125: 14 U/ml	Screening
FF	3	Inclusion criteria: 1/7	Screening
AA	2	SKB101 infusion: 710 mg	Visit 1
XX	1	Vital Signs: 1.71 m <sup>2</sup>	Visit 1
XX	1	Vital Signs: 11/27/2000	Visit 2

Validated Data

630C

630

Initials	Patient	Form	Visit
XX	1	Chem 20: 15mmol/l	Screening
XX	1	Exclusion criteria: ok	Screening
XX	1	GOG: 1	Screening
XX	1	history: 11/20/2000	All Visits
XX	1	history: 11/21/2000	Screening
XX	1	Tumor Assessment: 13 cm	Screening
fg	10	Vital Signs: 1.85 m <sup>2</sup>	Visit 1

Invalid Data

670

630D

Initials	Patient
BB	5
DD	8
DD	8
DD	8
DD	8
FG	10

Forms

650

Date 02/02/2001  
 Height 170 cm  
 Weight 160 lb  
 Temperature 99 F  
 Temperature site Oral  
 Pulse 65  
 Pulse type Regular  
 Respiration 45  
 Stop 135 mmHg  
 Dbp 70 mmHg

Visit
Screening
Visit 3
Visit 1
Screening
Visit 3
Screening

660

640

610

Figure 6

730
740
720

750
760A
760B

710

Vital Signs - Microsoft Internet Explorer
Print Help Back to list

**Vital Signs**

☒ ? Date  
☒ ? Height  
☒ ? Temperature  
☒ ? Temperature site  
☒ ? Pulse rate  
☒ ? Rhythm  
☒ ? Respiration  
☒ ? BP: SBP  
☒ ? BP: DBP

Patient #7    Screening    Validate    Help  
 01/22/2001    165 cm    60 kg    96 F    oral    58    regular    14    125 mmHg    65 mmHg

Click here to validate this value.  
(if conforms to the source documents)

	Visit5 +[6-8]	Visit6 +[6-8]	Visit7 +[6-8]	Last Visit +[6-8]
CBC				
Chem 20				
Toxicity Assessment				
Signoff				
Adverse events				
Other Medications				
Other Exams				

Sex: Female    Age: 45    End:

Inclusion: 12/28/2000

Figure 7

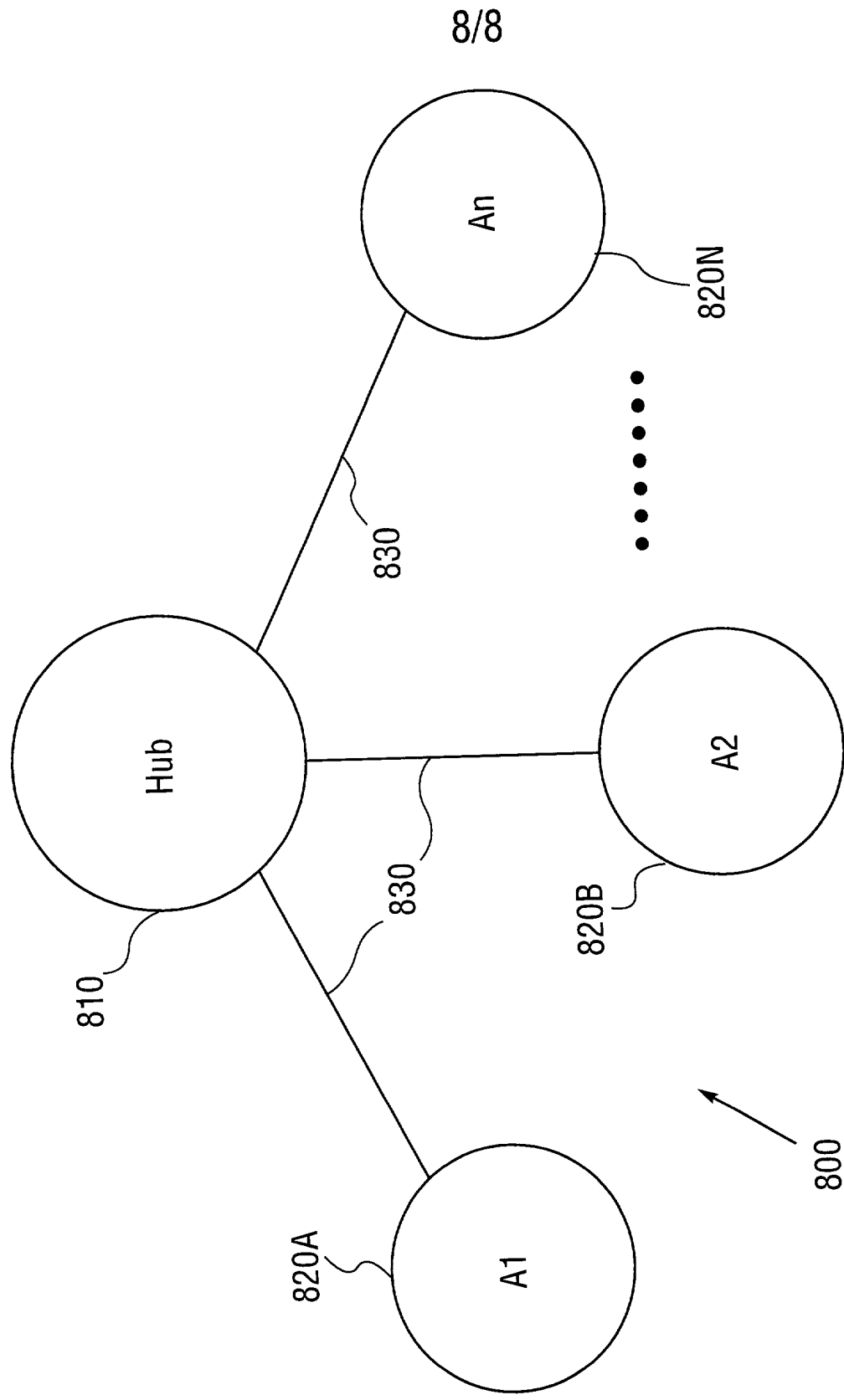


Figure 8